

REMARKS

Application Amendments

Claims 1 and 4 have been amended by way of the present amendments. Support for these amendments can be found in the claims as originally filed. No new matter has been added. Claims 1 to 17 are in the case.

The Rejection Under 35 USC § 112 First Paragraph

Claim 5 is rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is mostly nearly connected, to make and/or use the invention.

Specifically, the Examiner finds the phrase “a safe and effective amount” of the mixture of vitamin B3 compounds and retinoids for chronic use does not enable a skilled artisan to determine without undue experimentation what this amount should be. Applicants respectfully traverse this rejection based on the comments below.

One of ordinary skill in the art would understand from the disclosure that the term “safe and effective amount” means an amount of a compound, component, or composition sufficient to significantly induce a positive benefit, preferably a positive skin appearance or feel benefit, but low enough to avoid serious side effects, i.e., to provide a reasonable benefit to risk ratio, within the scope of sound medical judgment. See page 3, lines 23-27. Therefore, as long as the composition, compound or component contains an amount that is within scope of sound medical judgment they are suitable for the present invention. Applicants respectfully submit that the term objected to is fully defined, described and exemplified in the present specification. The term referred to is also a commonly used term in the art and would be readily understood by one of ordinary skill.

Moreover, 35 USC § 112 does not require Applicants to redefine in the claim each term when it is sufficiently defined in the specification as in the present case. In the case *In re Fuetterer*, 319 F. 2d 259, 138 U.S.P.Q. (BNA) 217 (C.C.P.A. 1963), the U.S. Court of Customs and Appeals decided a case in which the Examiner had rejected the

claim that contained "an **effective amount** ranging from more than incidental impurities". The Examiner stated that it would place an "undue burden...upon the public, to determine the operable proportions" that would enable the public to practice the invention. However, the U.S. Court of Customs and Appeal was not persuaded that any "undue burden" is placed on the public by the appellant's disclosure and rejected the Examiner's contention that the claims were indefinite and ambiguous. 35 U.S.C. 112 clearly indicates, in its first paragraph, that it is the function of the "written description" of the invention to "**enable**" one skilled in the pertinent art to "make and use" the invention and not that of the claims. This case has been subsequently followed by the C.A.F.C. in *In re Application of Herschler*, 591 F. 2d 693, 200 U.S.P.Q. (BNA) 711 (C.C.P.A. 1979) and *In re Anderson*, 471 F. 2d 1237, 176 U.S.P.Q. (BNA) 331 (C.C.P.A. 1973).

Accordingly, it is respectfully requested that this rejection be reconsidered and withdrawn.

The Rejection Under 35 USC § 112 Second Paragraph

Claims 1-17 are rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner finds the phrase "a whole number multiple thereof" renders the claim vague and confusing. The Applicants have removed this portion of the claim for reasons unrelated to patentability, thereby obviating the rejection.

The Rejections Under 35 USC § 103(a)

1. Kimura et al. US 5690916, Dietz et al. US 6132873 and JP 57098205 A (Pola Abstract)

Claims 1-3 and 9-17 are rejected as being unpatentable over Kimura et al. and Dietz et al. and JP 57098205 A. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the cosmetic composition in Kimura by substituting the interference pigments with the

interlayered pigments as taught by Dietz, because of the expectation of successfully producing an improved skin-color adjusting composition with stability, brighter color and greater intensity of the colors. Additionally, the Examiner states that the skilled artisan would have been further motivated to substitute the globular nylon powder for the spherical porous powder as suggested by the Pola abstract because of the expectation of successfully producing a cosmetic composition which provide longer cosmetic activity and good skin feel. Applicants respectfully traverse this rejection based on the amendments and remarks contained herein.

Specifically, the Examiner states that Kimura teaches a skin color adjusting composition comprising 5.0% of titanium-coated mica, 9.0% of titanium dioxide treated with silicone, and 5.0% of globular nylon powder. The Examiner states that the reference teaches that emulsion-type, water dispersed, and oil-dispersed foundations are conventional cosmetic formulations in which pigments are used and that the method of applying the composition to the skin to even the skin-tone is an obvious use of the invention. The Examiner concedes that Kimura does not teach the different weight ranges of the interference pigments and the inorganic powder. Kimura also fails to disclose interference pigments having a titanium dioxide layer of 120nm to about 160nm.

Kimura has extensive lists, column 9, line 3 to column 10, line 16, of all manners of components that could possibly be employed in the composition. Nothing in the disclosure would lead one to select the components of the present invention. "The citing reference that merely indicates that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." See *Ex parte Hiyamizu*, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note *In re Dembiczak* 175 F. 3d 994, 999 (Fed. Cir. 1999).

The interference pigments of the present invention are present in the range of from about 0.05% to about 2.5%. In contrast, the Kimura does not teach the amount of pigment that is required and only in the Examples do we see an amount which is at least 5%. Applicants have determined that the level of interference pigment is important in that the formula must be carefully balanced so that the role of the pigment, to reduce

redness on the hands, occurs without leaving too much residue. Too high of a level would give the skin an artificial look as well as leaving a residue on clothes that come into contact with it. Additionally, the present invention specifically requires that there can be no more than 3 % of the inorganic matting agent. See page 9, lines 5-6. Kimura teaches the use of at least 9% of the inorganic agent. See Examples 8 and 11. The increase of the inorganic matting agent could result in undesirable skin whitening giving the skin an unnaturally opaque appearance that is not the object of the present invention. See page 9, lines 5-8. The present invention is directed toward improving the appearance and feel of the skin on ones hands while retaining a natural skin appearance. See page 1, lines 8-11.

With special regard to Claim 13, the Examiner's attention is directed to the fact that the present invention are oil-in-water emulsions and Kimura is directed to water-in-oil emulsions. See page 7, lines 36-37.

Kimura does not teach or suggest the use of porous, nylon particles. The nylon particles of Kimura are globular nylon particles that are not disclosed as being porous. The present invention composition contains spherical porous, nylon particles as claimed in Claims 9 and 10. Applicants have determined that the spherical porous, nylon powders of the present invention reduce the sticky/tacky feel brought on by high levels of humectant or the presence of Niacinamide. The spherical porous powder has a ball bearing effect and provides a silky smooth feel during application. The powders of the Kimura reference are larger and produce a grainy product that results in a product that does not produce a smooth feel upon application.

The Examiner states that Dietz teaches multilayered interference pigments useful for cosmetic applications. Dietz teaches that the thickness of the layers of metal oxide of high refractive index is preferably between 40 and 260nm. Dietz further suggests that a skilled worker is able readily, by altering the layer thickness, to prepare a pigment with desired color and intensity. However, Dietz goes on to teach that this color shift plays no part in practice of the reference, since the end point is determined not by defined layer thickness but by the desired color (Column 4, line 29-31). Additionally, the Examiner states that due to the incorporation of the interlayer of a low-refractive index metal oxide, the pigments of the invention provide improved mechanical stability, brighter colors and

greater intensity of the colors than known interference pigments. The Examiner concedes that Dietz fails to teach porous nylon particles.

Dietz is directed to multilayered interference pigments that are useful in paints, printing inks, plastics, glazes for ceramics and glass as well as cosmetics. Dietz does not teach or suggest the use of porous, nylon particles. As discussed above, Applicants have determined that the spherical nylon powders reduce the sticky/tacky feel brought on by high levels of humectant or the presence of niacinamide and are in Claims 9 and 10. The improvements in skin feel are important to the present invention and Dietz does not teach or suggest the use of spherical porous nylon particles. One of ordinary skill in the art would have no motivation to use the particles of the present invention since Dietz does not disclose the use of any type of particle, and Kimura does not use spherical porous particles.

Combining the teachings of Kimura with the teachings of Dietz would not render the Applicants' presently claimed invention obvious. Specifically, the references do not teach or suggest a topical composition containing 0.05% to about 2.5% of interference pigments and 0.1% to 10% of a spherical porous nylon particle as in the present inventions Claims 9 and 10. Assuming that one having ordinary skill in the art would combine the disclosures of Kimura and Dietz one would still fall short of the Applicants' claimed invention only to arrive at a composition that is applied to the face, leaves too much residue and gives the skin an artificial look, a composition that is grainy and abrasive, and not smooth during application.

The Examiner states that the Pola abstract teaches cosmetics comprising spherical powder of porous resin, such as nylon, having an average particle size of 2-20 microns. Additionally, the Examiner states that Pola teaches that the porous powders are used in face powder or emulsion foundation, and provide, "prolonged cosmetic activity, good touch, high transparency, and high compatibility with the skin. The Examiner concedes that the abstract does not disclose the refractive index of the porous nylon powder.

Pola fails to disclose the amount of the spherical powder of porous resin that would be needed to provide the benefit to the skin. The present invention in Claim 1 requires 0.1% to 10% of the organic particulate. Additionally, Pola fails to disclose an organic particulate material with a refractive index of from 1.3 to 1.7. This index closely

matches the refractive index of the skin and Pola provides no suggestion or motivation to use particles that exhibit this property. Pola does not suggest or teach the use of interference pigments in the range of 0.05% to about 2.5%. As discussed previously, Applicants have determined that the level of interference pigment is important in that the formula must be carefully balanced so that the role of the pigment, to reduce redness on the hands, occurs without leaving too much residue. Too high a level would give the skin an artificial look as well as leaving residue on clothes. The present invention is directed toward a topical composition that provides for an improved composition which delivers immediate improvements in skin feel and appearance, particularly for non-facial parts of the body. See page 5, lines 1-2. The composition also provides for improved skin tone.

Combining the teachings of Kimura with the teachings of Dietz and Pola would not render the Applicants' presently claimed invention obvious. Specifically, the references do not teach or suggest a topical composition containing 0.05% to about 2.5% of interference pigments and 0.1% to 10% of a organic particulate material that as claimed in 9 and 10 are porous, nylon and spherical and have a refractive index of 1.3 to 1.7. Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Kimura, Dietz and Pola, one would still fall short of the Applicants' claimed invention only to arrive at a composition that is applied to the face, leaves too much residue and gives the skin an artificial look, a composition that is grainy and abrasive and not smooth during application, and does not match the refractive index of the skin. The references fail to teach or suggest each and every element of Applicants' presently claimed invention.

Accordingly, the Examiner has not presented a prima facie case of obviousness and Claims 1-3 and 9-17 of the present invention are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

2. Kimura et al. US 5690916, Dietz et al. US 6132873 and JP 57098205 A (Pola Abstract) and further in view of Nishimura et al. (JP 410194944 A, English Abstract of JP 10194944 A) and Mathur US 4096240

Claims 4-8 are rejected as being unpatentable over Kimura et al. and Dietz et al. and JP 57098205 A as applied to claims 1-3 and 9-17, and further in view of Nishimura et al. and Mathur. The Examiner concedes that Kimura and Dietz fail to teach the skin condition actives recited in the claims. The Examiner states that Nishimura teaches using anatase type titanium dioxide as an ultraviolet light protecting agent in cosmetics. Additionally, the Examiner states that Mathur teaches skin lightening compositions comprising niacinamide. The reference suggests employing from about 0.1-10% of the niacinamide. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding or substituting the matting agent therein with the anatase titanium dioxide of Nishimura and adding niacinamide as suggested by Mathur to come to the present invention. Applicants respectfully traverse this rejection based on the amendments and remarks contained herein.

At the outset, it is noted that the Examiner has not pointed to any disclosure in Nishimura or Mathur that would suggest modifying their disclosures to arrive at the present invention. Applicants assert that the arguments presented above regarding Kimura et al. and Dietz et al. and JP 57098205 A in traversing the § 103(a) rejection also apply to the present rejection. The references do not teach or suggest a topical composition containing 0.05% to about 2.5% of interference pigments and 0.1% to 10% of a spherical porous nylon particle with a refractive index of 1.3 to 1.7.

Nishimura is directed to a skin lotion that is either classified as medical or cosmetic. The anatase titanium dioxide is present from 1-20wt.%. The anatase titanium dioxide provides an ultraviolet light protecting agent. The present invention contains an anatase titanium dioxide that is treated with silicone and acts as a matting agent as claimed in Claims 3 and 4. See page 9, lines 4-8. The function of the silicone in the matting agent of the present invention is to hydrophobically-modify the pigments so that they are "wetttable" in the oil phase of an oil-in-water emulsion. See page 9, lines 21-29. The Nishimura reference does not teach or suggest the coating of the anatase titanium dioxide and the modification of the pigment as a result of this coating. One of ordinary skill in the art would have no motivation or suggestion based on the teachings in

Nishimura to alter the anatase titanium dioxide to arrive at presently claimed silicone treated anatase titanium dioxide that is "wetable".

Mathur is directed toward the application of a cosmetic composition containing niacinamide from about 0.1% to about 10% by weight of the composition and from about 0.1% to about 10% by weight of an ultraviolet absorbing sunscreen. The present invention contains from 0.1% to about 15% of the active. Additionally, Applicants have determined that the niacinamide of Claims 5, 6 and 7 of the present invention when used by itself gives rise to a sticky feel. See page 10, lines 1-4. The present invention alleviates this problem with the use of the spherical porous nylon particles that offset the sticky feel. See page 10, lines 3-4. Mathur does not disclose or suggest the use of spherical porous nylon particles to offset the sticky feel and there is no motivation for one with ordinary skill in the art to combine the teachings of Mathur with the previous references to arrive at a composition that alleviates the sticky feel. Specifically, there is never any suggestion or teaching that a sticky feel is a problem that needs to be alleviated within any of the cited references or that the incorporation of niacinamide actually causes a sticky feel. Since the cited references fail to teach or suggest the sticky feel caused by the incorporation of niacinamide or the need to alleviate the sticky feel, one of ordinary skill in the art would not be motivated to combine the previous art of record to arrive at the present invention.

Combining the teachings of Nishimura and Mathur with the previously discussed references would not render the present invention obvious. The references alone or in any combination fail to teach each and every element of Applicants' presently claimed invention.

Accordingly, the Examiner has not presented a prima facie case of obviousness and Claims 4-8 of the present invention are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

CONCLUSION

In light of the amendments to the claims and the remarks presented herein, Applicants respectfully submit that Claims 1-17 are allowable over the prior art of record.

Reconsideration is respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicants' undersigned attorney for further discussion.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A topical composition comprising:

- a) from 0.1% to 10% of an organic particulate material having a refractive index of from 1.3 to 1.7, the particulate material being dispersed in the composition and having a volume average particle size in the range of from about 10 to about 30 μm ;
- b) from about 0.05% to about 2.5% by weight of a green, platelet-type interference pigment material having a TiO_2 layer thickness of from about 120nm to about 160nm [or a whole number multiple thereof];
- c) from about 0% to about 3% of an inorganic matting agent; and
- d) a dermatologically acceptable, topical carrier.

4. (Amended) The composition of Claim 3 [1] wherein the inorganic matting agent is a titanium dioxide in its anatase form.